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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,908	08/15/2001	Diane McGhee	20518/9 (S-8457)	9256

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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/17/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,908

Applicant(s)

MCGHEE ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,24,25,42,43 and 45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-23,26-28 and 33-41 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 12-14, 15-17, 29-32, and 44 is/are rejected.
- 7) ☒ Claim(s) 4-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The examiner acknowledges receipt of Amendment A filed 9/2/03.

Election/Restrictions

1. This application contains claims drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 9, 12, 15, 17, 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox et al. (EP 038421).

Applicants claim a coating comprising a RTV silicone and urethane. The coating claimed by Applicants further comprises a pharmacological compound.

Fox discloses a method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents, especially a synergistic combination of a silver salt and chlorhexidine; also disclosed are medical devices the synergistic composition therein or compositions thereon. See Abstract. Biomedical silicones are disclosed on page 8. Fox also discloses a method of preparing an infection-resistant

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surface, characterized by preparing a coating vehicle by dispensing a matrix forming polymeric material selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof, in at least one solvent thereof, incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition, coating the surface with the coating composition, and drying the coating. See claim 1. The method of claim 1, characterized in that the matrix-forming polymeric material is a mixture of biomedical silicone and biomedical polyurethane. See claim 2. The method of according to any of claims 1-5, characterized in that the antimicrobial agent is selected from the group consisting of silver and its salts and penicillins. See claim 6. Therefore, these claims are anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 8-9, 12-14, 15-17, 29-32, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (EP 038421), and further in view of Remington's Pharmaceutical Sciences.

Fox discloses a method of preparing an infection-resistant medical device comprising one or more matrix-forming polymers selected from the group consisting of biomedical polyurethane, biomedical silicones and biodegradable polymers, and antimicrobial agents, especially a synergistic combination of a silver salt and chlorhexidine; also disclosed are medical devices the synergistic composition therein or compositions thereon. See Abstract. Fox also

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discloses a method of preparing an infection-resistant surface, characterized by preparing a coating vehicle by dispensing a matrix forming polymeric material selected from the group consisting of biomedical polyurethane, biomedical silicones, biodegradable polymers and combinations thereof, in at least one solvent thereof, incorporating at least one antimicrobial agent in the coating vehicle to form a coating composition, coating the surface with the coating composition, and drying the coating. See claim 1. The method of claim 1, characterized in that the matrix-forming polymeric material is a mixture of biomedical silicone and biomedical polyurethane. See claim 2. The method of according to any of claims 1-5, characterized in that the antimicrobial agent is selected from the group consisting of silver and its salts and penicillins. See claim 6. Suitable biomedical silicones include the silicone rubbers, specifically SILASTIC Type A Medical adhesive, a polydimethyl siloxane. See page 8. Solvents, such as hexane, are disclosed on page 11. Fox discloses the selection of a particular solvent or mixture of solvents will depend upon the specific biomedical polymeric coating agent being used as well as upon the particular antimicrobial agent or combination of agents. See page 11. The antimicrobial agents are disclosed on page 11. The antimicrobial agent is preferably employed in the coating vehicle at a level such that the final coating contains from about 10 to 70% by weight of the antimicrobial agent. See page 11. Fox does not disclose the addition of an emulsifier.

Remington's Pharmaceutical Sciences disclose emulsifying agents, which are surfactants and/or viscosity-producing agents. Emulsifying agents help stabilize a composition. See page 1304. Specific emulsifying agents include propylene glycol monostereate. See page 1307. Pigments are disclosed on page 1328, which are used to impart color.

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Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Fox by adding an emulsifier and a pigment as taught by Remington's because the expectation of stabilizing the composition as well as adding color as taught by Remington's.

Allowable Subject Matter

6. Claims 18-23, 26-28, 33-41 are allowed.
7. Claims 4-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 9/2/03 have been fully considered but they are not persuasive.

Rejection under 102(b)

Applicants argue Fox does not disclose the use of RTV silicone an urethane as claimed. The examiner refers to Fox, wherein Fox teaches the polymeric coating agent component of the coating vehicle is selected from the group consisting of biomedical polyurethanes, biomedical silicones, biodegradable polymers and combinations thereof. See page 3. Biomedical silicones are disclosed on page 8, including MDX4-4159 comprising a RTV silicone, polydimethyl siloxane copolymer and solvents. Therefore, it is the position of the examiner Fox teaches the combination of a RTV silicone and urethane. Thus, the rejection is maintained.

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Rejection under 103(a)

Applicants argue Fox teaches away from the instant invention. The examiner refers Fox, page 8, wherein Fox discloses biomedical silicones. Furthermore, Fox teaches the biomedical silicones are used in combination with the biomedical polyurethane. Therefore, it is the position of the examiner the reference does not teach away from the instant invention and the rejection is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

rmb


THURMAN K. PAGE
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